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CLAIMS

1. A method for obtaining a singular cell model capable of reproducing *in vitro* the metabolic idiosyncrasy of humans, wherein said model comprises a set of expression vectors that confer to the transformed cells a phenotypic profile of drug biotransformation enzymes designed at will, in order to reproduce the metabolic idiosyncrasy of humans, comprising:

a)   Transforming cells expressing reductase activity with a set of expression vectors comprising ectopic DNA sequence that code for drug biotransformation enzymes selected from among Phase I drug biotransformation enzyme and Phase II drug biotransformation enzyme ,

wherein each expression vector comprises an ectopic DNA sequence that codes for a different Phase I or Phase II drug biotransformation enzyme, selected from among:

(i)   a DNA sequence transcribed in the sense mRNA of a Phase I or Phase II drug biotransformation enzyme ("sense vector"); and

(ii)   a DNA sequence transcribed in the anti-sense mRNA of a Phase I or Phase II drug biotransformation enzyme ("anti-sense vector");

wherein the expression of said ectopic DNA sequences in the cells transformed with one ore more of the aforementioned expression vectors confers the transformed cells specific phenotypic profiles of Phase I or Phase II drug biotransformation enzymes,

to obtain with said expression vectors cells that transitorily express said ectopic DNA sequences and present a different phenotypic profile of Phase I or Phase II drug biotransformation enzymes, and

b)   building a singular cell model capable of reproducing *in vitro* the metabolic idiosyncrasy of humans from said cells transformed with the aforementioned set of expression vectors, both sense and anti-sense vectors, so that the result is the expression of any phenotypic profile of Phase I or Phase II drug biotransformation enzymes desired.

2. Method according to claim 1, wherein said cell expressing reductase activity is a human or animal cell, including tumour cells.

3. Method according to claim 1, wherein said cell expressing reductase activity is a human cell selected from among cells of hepatic, epithelial, endothelial and gastrointestinal type CaCO-2 cells.

4. Method, according to claim 1, wherein said Phase I and Phase II drug biotransformation enzymes are selected from among oxygenases, oxydases, hydrolases and conjugation enzymes.

5. Method according to claim 1, wherein said Phase I and Phase II drug biotransformation enzymes are selected from among monooxygenases dependent on CYP450, flavin-monooxygenases, sulfo-transferases, cytochrome C reductase, UDP-glucoronyl transferase, epoxide hydrolase and glutation transferase.

6. Method according to claim 1, wherein said ectopic DNA sequence coding for a Phase I or Phase II drug biotransformation enzyme is selected from among the group of DNA sequences transcribed in the sense mRNA or anti-sense mRNA of CYP450 isoenzymes and DNA sequences transcribed in the sense mRNA or anti-sense mRNA of oxygenases, oxidases, hydrolases and conjugation enzymes involved in drug biotransformation.

7. Method according to claim 1, wherein said ectopic DNA sequence coding for a Phase I or Phase II drug biotransformation enzyme is selected from among the group of DNA sequences transcribed in the sense mRNA or anti-sense mRNA of CYP 1A1, CYP 1A2, CYP 2A6, CYP 2B6, CYP 2C8, CYP 2C9, CYP 2C18, CYP 2C19, CYP 2D6, CYP 2E1, CYP 3A4, CYP 3A5, GST(A1), and DNA sequences transcribed in the sense mRNA or anti-sense mRNA of flavin-monooxygenases, sulfo-transferases, cytochrome C reductase, UDP-glucoronyl transferase, epoxide hydrolase or glutation transferase.

8. Method according to claim 1, wherein said ectopic DNA sequence coding for a Phase I or Phase II drug biotransformation enzyme is a DNA sequence transcribed in the sense mRNA of a Phase I or Phase II drug biotransformation enzyme.

9. Method according to claim 1, wherein said ectopic DNA sequence coding for a Phase I or Phase II drug biotransformation enzyme is a DNA sequence transcribed in the anti-sense mRNA of a Phase I or Phase II drug biotransformation enzyme.

10. Method according to claim 1, wherein said expression vectors comprising ectopic DNA sequences coding for the drug biotransformation enzymes selected from among Phase I drug biotransformation enzymes and Phase II drug biotransformation enzymes are selected from among viral vectors, liposomes and micellar vehicles.

11. Method according to claim 10, wherein said expression vectors are natural or recombinant adenoviruses.

12. Method according to claim 1, which comprises the combined use of variable amounts of said expression vectors comprising ectopic DNA sequences coding for the drug biotransformation enzymes selected from among Phase I drug biotransformation enzymes and Phase II drug biotransformation enzymes.

13. Use of sense or anti-sense expression vectors of Phase I or Phase II drug biotransformation enzymes in the manipulation of cells expressing reductase activity to reproduce in them the metabolic variability found in humans.

14. A method for studying the metabolism and/or pharmacokinetics and/or potential idiosyncratic hepatotoxicity and/or potential medicament interactions of a drug, which comprises placing said drug in contact with a singular cell model capable of reproducing *in vitro* the metabolic idiosyncrasy of humans obtained according to the method of any of claims 1 to 12.

15. A kit comprised of one or more expression vectors coding for the sense and anti-sense mRNA of the Phase I and Phase II drug biotransformation enzymes.

16. A method to confer to any cell line the capacity to metabolize xenobiotics in a controllable manner by means of an adenoviral set of expression vectors of Phase I and Phase II enzymes, as well as of cytochrome P450 reductase, comprising the transfection of said cell type with said adenoviral expression vectors in order to confer to the transformed cells a phenotypic profile designed at will, up to metabolize xenobiotics characterised in that depending on the characteristics of the cell type to be transformed one of the following situations can be expected:

a) the transformation of a cell type expressing cytochrome P450 reductase activity with a set of expression vectors comprising ectopic DNA sequences coding for P450 enzymes involved in the xenobiotic biotransformation, wherein each expression vector

comprises an ectopic DNA sequence transcribing for the sense mRNA of a different CYP enzyme,

b) the transformation of a cell type with a set of expression vectors comprising ectopic DNA sequences coding for drug biotransformation enzymes selected from among Phase I or Phase II enzymes, wherein each expression vector comprises an ectopic DNA sequence transcribing for the sense mRNA of a different Phase I or Phase II drug biotransformation enzyme,

c) the transformation of a cell type containing CYP genes but not expressing CYP reductase with a set of expression vectors comprising ectopic DNA sequences coding for said CYP enzyme, as well as sequences coding for CYP reductase, wherein each expression vector comprises an ectopic DNA sequence transcribing for either the sense mRNA of a CYP enzyme or the sense mRNA of a CYP reductase,

wherein the expression of all of said ectopic sequences in the transformed cells confers to them a transitory xenobiotic metabolic profile.